

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: J. Villard et al. FILING DATE: 12/27/2004
SERIAL NO.: 10/500,577 DOCKET NO: 6100-009
TITLE: Methods and Compositions to Reduce Scattering of Light During Therapeutic and Diagnostic Imaging Procedures

DECLARATION OF J. VILLARD UNDER 37 CFR §1.132

I, Joseph Villard, declare as follows:

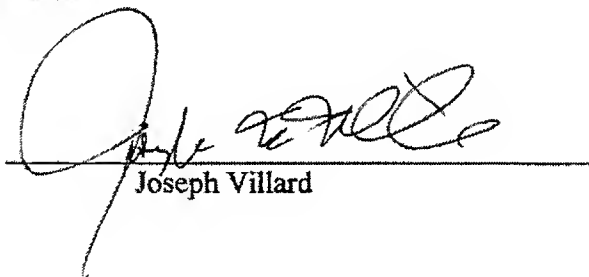
1. I am a resident of the State of Texas.
2. I graduated from the University of Texas at Austin with a Degree in Masters of Science in Engineering (Electrical Engineering), and I am currently employed as a Research Fellow working for The University of Texas Health Science Center in San Antonio.
3. My Curriculum Vitae is submitted herewith and designated as Exhibit A.
4. I am aware of and understand that the above-identified patent application (hereinafter referred to as "the Application") relates to a Methods and Compositions to Reduce Scattering of Light During Therapeutic and Diagnostic Imaging Procedures.
5. I am aware of Villard Masters Thesis, "Use of a Blood Substitute to Determine Instantaneous Murine Ventricular Thickening with Optical Coherence Tomography," The University of Texas at Austin, submitted August, 2001; (hereinafter the Villard '2001 reference), which was cited by the Examiner in the Office Action dated November 17, 2008 to form the basis for 35 U.S.C. §102(a) rejection against pending claims 1-4, 7-9, 11-31, 75, & 79-82 of the Application.
6. I am the author of the reference the Villard '2001 reference, which was submitted August of 2001 at the University of Texas. To the best of my knowledge, the Villard '2001 reference was released between January 2002 and July 2002.
7. I understand the pending claims of the Application are directed, in general, towards a method and composition of reducing scattering of light during therapeutic and diagnostic

imaging procedures. More specifically, the method (as recited in independent claims 1 of the Application) includes, *inter alia*, for performing optical imaging or treatment of at least a first tissue in an animal, comprising providing into the blood associated with said at least a first tissue a biologically effective amount of a low-scattering, oxygen-carrying blood substitute, and applying an optical imaging or treatment step to said at least a first tissue.

8. I am a co-inventor of the claims 1-82 in the Application and contributed towards the conception of the claims, including the claims as amended submitted February 17, 2009.
9. The Villard '2001 reference discloses subject matter derived from my research and conceptions. The relevant portions of the Villard '2001 reference originated with my research and conception of the using of a blood substitute to determine instantaneous murine ventricular thickening with Optical Coherence Tomography. I conceived of using Oxyglobin® [low-scattering, oxygen-carrying blood substitute] for OCT imaging of murine ventricle thickening.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Dated: February 12, 2009



Joseph Villard

Joseph W Villard MD, MSE

Summary

Physician/Engineer from a top 5 medical school and a top 10 electrical engineering program looking for a job in the medical device industry.

Experience

7/04 – 1/07 MVP Network, LLC. Saint Louis, MO

Director of Product Development

- Started and directed a video game development studio with \$1 million yearly budget
 - Hired, trained, and managed a team of 50+ game developers including programmers, graphic artists, sound artists, animators, and designers
 - Directed distributed team in the creation of online, multiplayer video games with enterprise-level sophistication
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9/01 – 8/02 Washington University, Division of Cardiothoracic Surgery Saint Louis, MO

Medical Student Research Assistant

- Conducted laparoscopic and robotic surgery drills with surgically naïve / trained participants
 - Performed animal experiments to test bipolar radiofrequency ablation applications in A Fib
 - Performed animal experiments to test Washington University heart transplant storage solution
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9/99 – 8/01 University of Texas – Austin Austin, TX

Graduate Research Assistant

- Patented experimental optical technique used to measure regional heart mechanics in a transgenic mouse model
 - Performed a pilot study to determine irradiation thresholds of PWS lesions associated with coincident cryogen spray cooling
-

Education

9/01-5/08 Washington University in Saint Louis Saint Louis, MO

Doctor of Medicine

9/99 – 5/01 University of Texas - Austin Austin, TX

Master of Science in Electrical Engineering

- NSF IGERT Graduate Fellowship
 - Thesis: Use of a Blood Substitute to Determine Instantaneous Murine Thickening with Optical Coherence Topography
-

9/94 – 5/99 Louisiana Tech University Ruston, LA

Joseph W Villard MD, MS

Bachelor of Science in Electrical Engineering

- National Merit Scholar and Frank T. Bogard Scholar
- Tau Beta Pi, Eta Kappa Nu
- Senior Project: Bioinstrumentation of fetal EKG monitoring

Relevant Skills

Software project management, analog and digital instrumentation, computer instrumentation interfacing, signal processing, image processing, computer programming (C/C++, Pascal, Assembly Language, LabView, MatLab), circuit design and analysis, optical instrumentation, laser-tissue interactions, Monte Carlo programming, small and large animal surgery

References

Available upon request.

Software Credits

Golden Fairway 3D. Published by MVP Online, Saint Louis, MO. August, 2006. Project Lead and Technical Lead. www.goldenfairway.com (use game code: egolf)

GT Racing Online. Published by MVP Online, Saint Louis, MO. December, 2007. Project Lead and Technical Lead. www.gtracingonline.com

Refereed Publications (chronological):

Cupps BP, Pomerantz BJ, Krock MD, Villard J, Rogers J, Moazami N, Pasque MK. Principal strain orientation in the normal human left ventricle. *Ann Thorac Surg*. 2005; 79(4):1338-43.

Villard JW, Feldman MD, Kim J, Milner TE, Freeman GL. Use of a blood substitute to determine instantaneous murine right ventricular thickening with optical coherence tomography. *Circulation*. 2002; 105(15):1843-9.

Abstracts, Posters, Presentations, and Conference Proceedings

Maniar HS, Prasad SM, Chu CM, Villard J, Klingensmith ME, Damiano RJ. Training with Robotic Systems. Poster Presentation at the Association for Academic Surgery, Boston, Massachusetts, November 2002.

Prasad SM, Maniar HS, Villard JW, Gabbard J, Schuessler RB, Damiano RJ. Myocardial Ablation With Bipolar Radiofrequency Ablation: Evaluation of Ablation Depth and Width Using Conductance Based Dosimetry. Poster Presentation at the 8th Annual Meeting of Cardiothoracic Techniques & Technologies: Current Trends in Thoracic Surgery VIII, in Fort Lauderdale, Florida, January 23-26, 2002.

Kim J, Villard JW, Feldman MD, Escobedo D, Freeman GL, Milner TE. Murine myocardium OCT imaging with a blood substitute. Coherence Domain Optical Methods in Biomedical Science and Clinical Applications VI. Proceedings of SPIE volume number 4619; [4619-32]. Presented January 23rd, 2002. San Jose, CA.

Patents

Villard JW, Feldman MD, Milner TE. Methods and compositions to reduce scattering of light during therapeutic and diagnostic imaging procedures. United States Patent Application #20050113678. May 26, 2005.